Sydney Health Partners

Maridulu Budyari Gumal
Working together for good health and wellbeing

HREC Leaders '22

Inaugural State-wide Summit

Program

26 OCTOBER 2022: UNIVERSITY OF TECHNOLOGY, SYDNEY

Where:
UTS Aerial Function Centre, Level 7, 235 Jones Street Ultimo
(UTS Building 10)

Time:
Registrations open 8.30 am
Program starts at 9.30am - 3.30 pm followed by a networking afternoon tea.

Join HREC Chairs and research ethics leaders from across NSW for a unique day of learning, discussions and networking whilst celebrating the valuable role that ethics committees play in research.

You will hear from speakers with extensive experience on research ethics committees, and get a chance to collaborate in facilitated workshops examining matters of mutual ambition. Workshop session themes will be: Engaging researchers in ethics review; Best practice involving consumers; Ethical issues of consent and data sharing; The ethical challenges raised by new research methods.

You'll be challenged by new approaches and encouraged to find solutions to those 'tricky' issues that can both help and impede ethics deliberations.

Whether you're a new HREC Chair or RGO leader, or come with a wealth of expertise, we invite you to share your knowledge and build connections with your peers from across the State.

Highlights of the day's program

Keynote speaker **Prof Ingrid Winship** will open the Summit with a discussion on Framing research ethics 2022 and beyond.

Dr Karolyn White, Director, Research Ethics and Integrity, Macquarie University will invite participants to share their experiences of the 'tricky issues' that arise in ethics review.

Associate Professor Sarah Garnett and **Dr Barbara Ann Adelstein** will reflect on their experience of chairing ethics committees and lead a discussion of the value that ethics review makes to good research practice and outcomes.

Two sessions of workshops will be held. The workshop themes are:

- Engaging researchers in the ethics review process
- The ethical issues of consent and data sharing
- Ethical challenges raised by new research methods
- Best practice involving consumers

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Program summary

8.30 am	Registration
9.30 am	Summit opens
9.45 am	Keynote speaker Prof Ingrid Winship. Framing research ethics 2022 and beyond.
11.05 am	Join session 1 workshop themes
12.00 noon	Join session 2 workshop themes
	Lunch and networking
1.30 pm	Morning wrap up.
1.40 pm	Same rules, different outcomes. Facilitated discussion of the 'tricky issues' that arise in ethics review.
2.30 pm	The value-add of human research ethics committees. A discussion of the value that ethics review makes to good research practice and outcomes.
3.20 pm	Afternoon wrap up.
3.30 pm	Afternoon tea and networking
4.10 pm	Summit close

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Choose your Workshops

Two sessions of workshops will be held. Register your preferences from the list below, one workshop from each session. Numbers per workshop are capped.

Session 1.

The pros and cons of inviting researchers to attend HREC meetings

Facilitators: Prof Murray Killingsworth, HREC Chair SWSLHD and Ms Annamarie D'Souza, Research Development Manager, SWSLHD.

Under the heading Good communication between review bodies and researchers, the National Statement (sections 5.2.14-16 and 5.2.20) outlines that ethics committees and research office staff should endeavour to communicate with researchers in a number of ways and at a number of points in the ethics review process. One approach is to invite researchers to the HREC meeting to immediately clarify concerns and shorten the approval process. But what are the practicalities of this and can it really work? Has the widespread use of virtual meetings now made this possible? Professor Murray Killingsworth will lead a discussion on how NSW based HRECs and ethics secretariats are grappling with, or perhaps meeting, this challenge.

If your HREC is wondering how to embed this communication approach, or you have already done it and can lead the way for others, we'd love to have you at this workshop.

How to determine what is a clinical trial, and how to assess clinical trials and research design quality

Facilitators: Dr Tony Skapetis HREC Chair and Ms Kellie Hansen Research Manager, WSLHD.

The World Health Organization definition for a clinical trial is 'any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes'. The definition is clarified by noting more than nine types of interventions

that can be considered clinical trials including experimental drugs, medical devices, health service changes and educational interventions.

Does your ethics committee, or your researchers, sometimes struggle to determine whether an application should be considered and reviewed as a clinical trial? How does your committee determine if researchers have made the right design choices? How is the quality of the trial determined? Have researchers shown in their application that they understand the legal, institutional and professional obligations they have when conducting a clinical trial, including conducting the researcher under Good Clinical Practice guidelines?

Want to discuss more? Then this workshop is for you.

So many ways to say 'yes'. An in-depth look at the issue of consent

Facilitators: Assoc Professor Helen Mitchell and Mr Alan Hales, University of Sydney.

Join an HREC Chair and Ethics Manager in a discussion about niche research design areas and consent models, teasing out the many ways to approach informed consent in today's changing clinical trials environment.

The challenges raised by genetic research

Facilitator: Prof Ingrid Winship, Chair of Adult Clinical Genetics at the University of Melbourne and Director of Genomic Medicine at the Royal Melbourne Hospital.

Our keynote speaker will lead this workshop on ethics review considerations for genetic research.

Session 2.

Involving consumers in research design

Facilitator: Ms Carrie Hayter – Health Consumers NSW.

The involvement of consumers is now a recognised ingredient for effective and relevant research. How does an ethics committee determine whether researchers have met this responsibility in conceiving and developing their research protocol? What does best practice consumer involvement look like and how does an ethics committee approach an application that doesn't meet this standard?

This workshop will draw on the experience of all participants to develop an understanding of what best practice community involvement should look like and how ethics committees can work with researchers to bring all projects closer to this ideal.

Adaptive designs – embracing the trials and avoiding the tribulations

Facilitators: Prof Tom Snelling, University of Sydney and Dr Lucy Coupland, Maridulu Budyari Gumal.

The COVID-19 pandemic has brought into focus the significant benefits of adaptive trial designs. Such designs have a certain level of fluidity which increases the likelihood of a trial outcome. Additionally, platform trials provide a perpetual framework for multiple sub-trials that dramatically increases the pace of treatment evaluation and implementation into standard care. Adaptive trials may require significant biostatistical and trial coordinator expertise, as well as long-term financial support. They may also bring unique ethical issues to the table.

Prof Tom Snelling will provide an introduction to adaptive trial designs and the associated ethical issues, and one of his adaptive trial protocols will be dissected within the workshop.

Collaboration, connection and innovation in a data economy

Facilitators: Prof Angela Webster, University of Sydney and Dr Angela Todd, Sydney Health Partners.

So much data and so many ways to use it! The desirability of sharing research data has long been understood, but a number of hurdles still remain. Key issues for research participants and health consumers can be their right to privacy and the agreements made when the data was collected. For researchers, protecting their own interests when sharing data, and accessing datasets produced by others, can be difficult; and for institutions data management and security, and providing datasets, can be challenging.

A lot of work is underway across the sector to bring practice in line with the potential. Come along to discuss what's new and what's still challenging in this space.

SUcceSS. What lessons can be learned from the world's first randomised placebo-controlled surgical trial of lumbar spinal stenosis?

Facilitator: Prof Manuela Ferreira, University of Sydney.

Sham surgery and placebo trial designs require a participant to experience all aspects of a treatment except that which is believed to provide the therapeutic effect. They raise questions around the risk/benefit equation, the placebo effect and the process of informed consent.

How would your ethics committee respond to a research protocol involving sham surgery? Discuss the issues with a researcher who has conducted an ethics approved, world first trial using this research methodology.

Things happen! If workshop topics or speakers need to be adjusted we will endeavour to provide replacements of equal interest and calibre.